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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,823	08/28/2002	Michel Revel	REVEL=16	1533

1444 7590 10/20/2004

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,823	REVEL ET AL.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-12,14 and 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-12,14 and 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12/06/01* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

1a. Receipt of Applicants' amendment and arguments filed on 23 July 2004 is acknowledged.

Status of Claims:

1b. Claims 1-8 and 13 have been canceled. Claims 9-12, 14-15 are pending and under consideration.

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed on 07/23/04:

(I) The rejection of claims 9-13, 14-15 made under 35 U.S.C. 112, second paragraph, is withdrawn, because claim 9 now recites method steps; the full name of the interleukin-6 receptor chimera (IL6RIL6) is also recited in claim 9.

(II) The rejection of claims 9-12 and 14-15 made under 35 U.S.C § 102(b) as being anticipated by Revel et al (WO 99/02552, 01/21/1999), is withdrawn. Applicants' argument that the method of treating neurological disorders in general by administering the IL6RIL6 chimera does not anticipate the claimed method of inducing myelination and remyelination of neurons and treating the specific disorders that involve myelination such as MS, is persuasive. Revel et al reference does not teach or suggest that the IL6RIL6 chimera of the instant invention would be effective against demyelinating disease of the CNS and PNS, as demonstrated by the instant specification, (see Examples 1-8).

Claim rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claims 9-11, 14-15 stand rejected under 35 U.S.C. 112, first paragraph, for reasons of record set forth in the office action mailed on 23 February 2004, pages 2-4.

Applicants argue that the instant specification is enabling for a method of a treating demyelinating disease of the CNS and PNS, by administering IL6RIL6 chimera, as conceded by the Examiner, but is also enabling for a method of protection of neurons from pathological insults, for example excitotxicity (cell death caused by excessive activation of glutamate receptors), as is disclosed in Examples 9 and 10. Applicants contend that the instant specification demonstrates that the administration of IL6RIL6 chimera provides protection from NMDA-induced hippocampal cell death and from glutamate induced neurotxcocty and from toxicity caused by the withdrawal of NGF. Applicants submit a reference that describes a model for parkinson's disease, (Gerlach et al).

These arguments have been considered fully, but are not deemed persuasive. Applicants are arguing limitations not recited in the claims. The Examiner does not dispute that the instant specification is enabling for a method of protecting neurons from NMDA-induced cell death, from glutamate induced neurotoxicity and from toxicity caused by the withdrawal of NGF, however, these limitations are not recited in the instant claims. The instant claims 9 and 10 recite "....protecting neurons from pathological insults...", although the instant specification does not provide a description for this phrase, and the phrase does not seem to be an art recognized phrase, it

appears that this phrase encompasses "all possible" neurological damages, caused by "all possible" culprits. However, the instant specification demonstrates that the administration of IL6RIL6 chimera provides protection against neurotoxicity caused by excitatory amino acids, such as glutamate induced neurotoxicity, NMDA-induced cell death and from toxicity caused by NGF withdrawal. Again, it is not disputed that excitotoxicity might be a mechanism of cell death in Parkinson's disease and similar diseases, as described by the cited reference and as demonstrated in Example 9 of the instant specification. However, the instant specification is not enabling a method of protecting neurons from "all possible" pathological insults. With respect to claim 11, which recites "....traumatic nerve degeneration.....", the instant specification is not enabling for protecting a patient from "all possible" traumatic nerve degeneration diseases.

Therefore, it is not predictable from the experiments in the instant specification that IL6RIL6 chimera of the instant invention would protect neurons from "all possible" pathological insults. The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. In the instant case, due to the complexity of the neurodegenrative diseases, and due to the fact that

instant specification only discloses that the IL6RIL6 chimera might be effective against diseases caused by demyeliantion, and also protectes neurons from NMDA-induced cell death, from glutamate induced neurotoxicity and from toxicity caused by the withdrawal of NGF, undue experimentation would be required for the skilled artisan to test whether IL6RIL6 chimera protects neurons form "all" possible pathological insults and from "all possible" traumatic nerve degeneration diseases. Thus instant specification is only enabling for a method of treating a demylinating disease of the central nervous system (CNS) or peripheral nervous system (PNS), and a method of protecting neurons from NMDA-induced cell death, and from glutamate induced neurotoxicity and from toxicity caused by the withdrawal of NGF said method comprising administering an effective amount of interleukin-6 receptor/interleukin-6 chimera (IL6RIL6).

Conclusion:

4. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
18 October 2004

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER